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10/529,483	03/28/2005	Atsunori Hiratsuka	2005_0468A	7927

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EXAMINER	
BALL, JOHN C	

ART UNIT	PAPER NUMBER
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,483	HIRATSUKA ET AL.	
	Examiner	Art Unit	
	J. CHRISTOPHER BALL	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/28/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. This is the initial Office Action based on the HIRATSUKA et al. application filed under the Patent Cooperation Treaty on April 26, 2004, and received as a National Stage Application ("371") with the Office on March 28, 2005.

2. Claims 1-23 are currently pending and have been fully considered.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by an English translation of OTSUKA et al. (Japanese Published Patent Application 2003-102710, A).

Regarding claim 1, OTSUKA discloses a blood analysis system wherein the system is taught to comprise a filter for filtering a blood sample (103, Drawings 1 and 2), comprising:

a channel for causing the blood sample to flow (110, Drawings 3-9);

an implicit opening for introducing the blood sample, the opening being located at one end of the channel (124, Drawings 3-9); and

an implicit opening for discharging the blood sample filtered through the channel, the opening being located at the other end of the channel (end opposite element 124, Drawings 3-9),

wherein a plurality of structures are disposed in the channel to prevent the blood cell component from passing through the channel (111, 113, and 115, Drawings 3 and 7),

the structures are disposed at intervals such that a slit through which the blood cell component cannot pass is formed between each structure and an adjacent inner wall of the channel and between adjacent structures (Drawings 3 and 7), and

the plurality of structures and the inner wall of the channel define at least one cavity functioning as a blood cell reservoir for accommodating the blood cell component in the channel (118, 119, and 120, Drawings 3 and7).

Regarding claim 2, OTSUKA teaches at least two cavities are defined in the channel (118, 119, and 120, Drawings 3 and 7) .

Regarding claim 3, OTSUKA teaches the depth of the cavity is greater than the width of a mouth of the cavity (118, 119, and 120, Drawing 7).

Regarding claim 5, OTSUKA teaches the cavity is in a shape of substantially a rectangular parallelepiped (118, 119, and 120, Drawing 7).

Regarding claim 7, OTSUKA teaches the channel is formed by a substrate (101, Drawings 1 and 2) and a cover attached to the substrate (paragraph [0028]), where implicitly a spacer must be included to keep form a channel in between the substrate and cover.

Regarding claim 8, OTSUKA teaches the structures are in the shape of columns (111, 113, and 115, Drawings 3 and 7).

6. Claims 1, 7, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by BHULLAR et al. (US 6,319,719 B1).

Regarding claim 1, BHULLAR discloses a capillary hematocrit separation structure, comprising:

a channel for causing the blood sample to flow (24, Figure 2);

an opening for introducing the blood sample, the opening being located at one end of the channel (18, Figure 2); and

an opening for discharging the blood sample filtered through the channel, the opening being located at the other end of the channel (20, Figure 2),

wherein a plurality of structures are disposed in the channel (30, Figure 2) to prevent the blood cell component from passing through the channel (Col. 5, lines 18-29),

the structures are disposed at intervals such that a slit through which the blood cell component cannot pass is formed between each structure and an adjacent inner wall of the channel and between adjacent structures (Figure 2), and

the plurality of structures and the inner wall of the channel define at least one cavity functioning as a blood cell reservoir for accommodating the blood cell component in the channel (Col. 5, lines 18-21).

Regarding claim 7, BHULLAR teaches the channel is formed by a substrate (the bottom of 12, Figure 6E), a spacer (outer side walls of 12, Figure 6E), and a cover attached to the substrate via the spacer (14, Figure 1).

Regarding claim 10, BHULLAR teaches the blood sample is introduced into the channel by capillary action (Col. 5, lines 15-18).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 4, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over an English translation of OTSUKA et al. (Japanese Published Patent Application 2003-102710, A).

Regarding claims 4 and 6, OTSUKA teaches the limitations of claim 1, as outlined above.

OTSUKA is silent as to the dimensions of the cavity mouth and width of the slits.

However, one of ordinary skill would recognize that the dimension of these two elements are definable as result effective variables, as changes to their

dimensions will effect the separation performance of the device. As such, a person of ordinary skill in the art would vary the dimensions of both the mouth of the cavity and the width of the slits without undue experimentation to optimize the size to result in the desired separation. It would therefore be obvious that one of ordinary skill in the art would use mouth of cavity dimensions in the range of 2 to 10 μm, and width of the slits in the range of 0.1 to 2 μm.

Regarding claim 9, OTSUKA discloses rectangular columns as the shape of the columns (111, 113, and 115, Drawings 3 and 7), and does not explicitly teach the structures are in the shape of a cylinder.

However, the shape of the structures would be a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration, namely a cylinder, is significant over any other choice. Lacking such evidence in the present specification, a skilled artisan would be able to choose to use a different shaped structure than the column as taught by OTSUKA, including the use of a cylinder shape. (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

10. Claims 6 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over BHULLAR et al. (US 6,319,719 B1).

Regarding claim 6, BHULLAR teaches the limitations of claim 1, as outlined above. BHULLAR also teaches the width of the slits is about 10 μm (Col. 4, lines 39-40).

BHULLAR does not explicitly teach the width of the slits is in the range of about 0.1 μm to about 2 μm.

However, one of ordinary skill would recognize that the dimension of the width of the slits are definable as result effective variables, as changes to their dimensions will effect the separation performance of the device. As such, a person of ordinary skill in the art would vary the dimensions of the width of the slits without undue experimentation to optimize the size to result in the desired separation. It would therefore be obvious that one of ordinary skill in the art would use width of the slits in the range of 0.1 to 2 μm.

Regarding claim 11, BHULLAR teaches the limitations of claim 1, as outlined above. BHULLAR also teaches that the apparatus can be formed from polycarbonate as an example (Col. 4, lines 59-62).

BHULLAR does not explicitly teach the structures and inner wall of the channel are made of silicone resin, Teflon, or epoxy resin.

However, it would have been obvious to one of ordinary skill in the art to form the structures and inner wall of the channel out of silicone resin, Teflon, or epoxy resin as a substitution of the polycarbonate as taught by BHULLAR as this would be substituting one known polymer, polycarbonate, for another known polymer, any of silicone resin, Teflon, or epoxy resin, with the expectation of yielding predictable results. (*KSR International Co. v. Teleflex Inc., 550 U.S.__, 82 USPQ2d 1385 (2007)*)

11. Claims 12-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over BHULLAR et al. (US 6,755,949 B1; herein after referred to as " '949") in view of an English translation of OTSUKA et al. (Japanese Published Patent Application 2003-102710, A).

Regarding claims 12 and 13, Patent '949 discloses a biosensor, wherein the biosensor is taught comprising:

a substrate (Col. 3, lines 4-5);

a measuring system, comprising an electrode system including a pair of electrodes, supported on the substrate (Col. 3, lines 22-24);

a reagent system containing a redox enzyme (Col. 6, lines 37-48) supported by the measuring system (Col. 6, lines 24-25);

a cover (56, Figure 2A) combined with a substrate (12, Figure 2A) to define, therebetween, a filter region for removing the blood cell components from a blood sample (Col. 5, lines 26-35), a reaction region (34, Figure 2A) for accommodating the measuring system and the reagent system, and a sample introduction pathway connected to the filter region for introducing the sample to the reaction region (where channel, 60, meets reaction reagent, 34, Figure 3),

the filter region is defined by :

a channel for causing the blood sample to flow (60, Figure 3);

an opening for introducing the blood sample, the opening being located at one end of the channel (opening at end, 50, Figure 3);

an opening being located at the other end of the channel (toward end 52, Figure 3) and being connected to the sample introduction pathway (where channel, 60, meets reaction reagent, 34, Figure 3); and

a plurality of structures disposed in the channel to prevent the blood cell component from passing through the channel (Col. 4, lines 16-30 & Col. 5, lines 26-35);

the structures are disposed at intervals such that a slit through which the blood cell component cannot pass is formed between each structure and an adjacent inner wall of the channel or between adjacent structures (evident in Figures 2B, 5, and 6).

'949 does not explicitly teach the plurality of structures and the inner wall of the channel define at least one cavity functioning as a blood cell reservoir for accommodating the blood cell component in the channel.

However, OTSUKA discloses a blood analysis system wherein the system is taught to comprise the plurality of structures and the inner wall of the channel define at least one cavity functioning as a blood cell reservoir for accommodating the blood cell component in the channel (118, 119, and 120, Drawings 3 and7).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the device as taught by '949 with the cavities as taught by OTSUKA because the cavities varying in size to effectively filter blood cell components of various sizes.

Regarding claim 14, modified '949 teaches the limitations of claim 12, as outlined above.

'949 does not teach two cavities are defined in the channel.

However, OTSUKA teaches at least two cavities are defined in the channel (118, 119, and 120, Drawings 3 and 7).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the device as taught by '949 with the cavities as taught by OTSUKA because the cavities varying in size to effectively filter blood cell components of various sizes.

Regarding claim 15, modified '949 teaches the limitations of claim 12, as outlined above.

'949 does not teach the depth of the cavity is greater than the width of a mouth of the cavity.

However, OTSUKA teaches the depth of the cavity is greater than the width of a mouth of the cavity (118, 119, and 120, Drawing 7).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the device as taught by '949 with the cavities as taught by OTSUKA because the cavities varying in size to effectively filter blood cell components of various sizes.

Regarding claims 16 and 18, modified '949 teaches the limitations of claim 12, as outlined above.

OTSUKA teaches a cavity functioning as a blood cell reservoir for accommodating the blood cell component in the channel (118, 119, and 120, Drawings 3 and7). Neither '949 nor OTSUKA teaches the dimensions of the cavity mouth and width of the slits.

However, one of ordinary skill would recognize that the dimension of these two elements are definable as result effective variables, as changes to their dimensions will effect the separation performance of the device. As such, a person of ordinary skill in the art would vary the dimensions of both the mouth of the cavity and the width of the slits without undue experimentation to optimize the

size to result in the desired separation. It would therefore be obvious that one of ordinary skill in the art would use mouth of cavity dimensions in the range of 2 to 10 μm, and width of the slits in the range of 0.1 to 2 μm.

Regarding claim 17, modified '949 teaches the limitations of claim 12, as outlined above.

'949 does not teach the cavity is in a shape of substantially a rectangular parallelepiped.

However, OTSUKA teaches the cavity is in a shape of substantially a rectangular parallelepiped (118, 119, and 120, Drawing 7).

At the time of the present invention, it would have been obvious to one of ordinary skill in the art to modify the device as taught by '949 with the cavities as taught by OTSUKA because the cavities varying in size to effectively filter blood cell components of various sizes.

Regarding claim 19, '949 teaches a substrate (bottom of 40, Figure 2B), a spacer, in the form of sidewalls (44, Figure 2B), and a cover (56, Figure 2B) attached to the substrate via the spacer (Figure 1).

Regarding claim 20, '949 teaches the structures are in the shape of columns (Figures 2B, 5, and 6).

Regarding claim 21, '949 teaches the structures can assume a variety of shapes (Col. 4, lines 31-33). The shape of the structures would be a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration, namely a cylinder, is significant over any other choice. Lacking such evidence in the present specification, a skilled artisan would be able to choose to use a different shaped structure than the column as taught by '949, including the use of a cylinder shape. (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Regarding claim 22, '949 teaches the channel is a capillary channel (Col. 4, lines 65-67); therefore the sample would inherently be introduced by capillary action.

Regarding claim 23, '949 teaches the structures and inner wall can be constructed from a variety of insulative materials, including a number of polymers (Col. 3, lines 8-14).

'949 does not explicitly teach the structures and inner wall of the channel are made of silicone resin, Teflon, or epoxy resin.

However, it would have been obvious to one of ordinary skill in the art to form the structures and inner wall of the channel out of silicone resin, Teflon, or epoxy resin as a substitution of the polymers as taught by '949 as this would be substituting one known polymer for another known polymer, any of silicone resin,

Teflon, or epoxy resin, with the expectation of yielding predictable results. (*KSR International Co. v. Teleflex Inc., 550 U.S.__, 82 USPQ2d 1385 (2007)*)

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. CHRISTOPHER BALL whose telephone number is (571)270-5119. The examiner can normally be reached on Monday through Thursday, 8:00 am to 5:00 pm (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JCB
AU 1795
03/13/2009

/Alex Noguerola/
Primary Examiner, Art Unit 1795
March 16, 2009